

REMARKS

Applicant and the undersigned thank Examiner Fan for the courtesies extended in today's interview. This Supplemental Amendment is submitted in response to the issues discussed in the interview. Applicant hereby incorporates its Remarks from prior amendments (including that of this morning's Amendment and Response) as if fully set forth herein. None of the amendments are to be construed as dedicating any unclaimed subject matter to the public, and Applicant reserves all rights to pursue any such unclaimed subject matter in this or a related case.

No new matter is raised by these amendments.

As was discussed during today's interview, support for the above amendments appear on at least the following pages of the Specification:

- Page 28 Page 28, lines 18-21: "The dosage range of omeprazole or other proton pump inhibitors such as substituted benzimidazoles and derivatives thereof can range from approximately <2 mg/day to approximately 300 mg/day."
- Page 31 states that the solution can be formulated with 5% to 60% sodium bicarbonate, which equates to about 5 mEq to about 70 mEq per 10 ml dose of omeprazole.
- Page 32, lines 1-5: "approximately 1 mEq . . . sodium bicarbonate per 2 mg omeprazole with a range of approximately 0.2 mEq . . . to 5 mEq . . . per 2 mg omeprazole."
- Page 33, lines 26-29: "The omeprazole or other PPIs and buffering agent can be formed into a tablet, capsule"
- Page 26, lines 28-30: "The inventive compositions comprise dry forms, solutions and/or suspensions of the proton pump inhibitors."
- Pages 45-47: Solid dosage form Examples.

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With entry of the above Amendment and in view of the foregoing remarks, it is respectfully submitted that claims the pending claims are in condition for allowance.

Also submitted below, on a separate page titled "Version with Marking to Show Changes Made to the Claims," is a marked-up copy of prior pending claims. It is respectfully submitted in view of the foregoing Amendment and Remarks that all of the objections and rejections in the Office Action dated February 1, 2001 have been overcome and should be withdrawn. Applicant respectfully requests early and favorable notification to that effect. The Examiner is encouraged to contact the undersigned with any questions or to otherwise expedite prosecution.

Respectfully submitted,

THE CURATORS OF THE
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By: MAYER, BROWN, ROWE & MAW,

By:


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Dated: March 25, 2002

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Version with Markings to Show Changes Made to the Claims

23. (Amended fourth time) A solid pharmaceutical composition in a dosage form that is not enteric-coated, comprising: active ingredients consisting essentially of:

(a) a non-enteric coated proton pump inhibitor selected from the group consisting of omeprazole, lansoprazole, rabeprazole, esomeprazole, pantoprazole, pariprazole, and leminoprazole, or an enantiomer, isomer, derivative, free base, or salt thereof, in an amount of approximately 5 mg to approximately 300 mg; and

(b) at least one buffering agent selected from the group consisting of sodium bicarbonate, potassium bicarbonate, a calcium salt, and a magnesium salt, in an amount of approximately 0.1 mEq to approximately 2.5 mEq per mg of proton pump inhibitor [provided that the buffering agent is in an amount sufficient to elevate gastric acid pH of the subject's stomach to prevent or inhibit gastric acid degradation of the non-enteric coated proton pump inhibitor and achieve sufficient bioavailability of the proton pump inhibitor in the subject to elicit a therapeutic effect];

wherein the dosage form is selected from the group consisting of suspension tablet, chewable tablet, effervescent powder, and effervescent tablet.

622. (Amended twice) A method for treating an acid-caused gastrointestinal disorder in a subject in need thereof, comprising: administering to the subject a solid pharmaceutical composition in a dosage form that is not enteric-coated; wherein the composition comprises active ingredients consisting essentially of:

(a) a therapeutically effective amount of approximately 5 mg to approximately 300 mg of a non-enteric coated proton pump inhibitor selected from the group consisting of

omeprazole, lansoprazole, rabeprazole, esomeprazole, pantoprazole, pariprazole, and leminoprazole, or an enantiomer, isomer, derivative, free base, or salt thereof; and

(b) a buffering agent in an amount of approximately 1.0 mEq to approximately 150 mEq selected from the group consisting of a bicarbonate salt of a group IA metal, a calcium salt, and a magnesium salt, wherein the buffering agent is in an amount sufficient to elevate gastric acid pH of the subject's stomach to prevent or inhibit gastric acid degradation of the non-enteric coated proton pump inhibitor and achieve sufficient bioavailability of the proton pump inhibitor in the subject to elicit a therapeutic effect.

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